

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Lee T. Bachler et al.

Application No.: 10/598,479

Confirmation No.: 5991

Filed: August 31, 2006

Art Unit: 1631

For: ESTIMATION OF CLINICAL CUT-OFFS

Examiner: J. LIN

**APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST
FOR RECONSIDERATION UNDER 37 C.F.R. §1.705(b)**

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. This is a request for reconsideration of the patent term adjustment of 712 days indicated in the “Determination of Patent Term Adjustment under 35 USC 154(b)” that was attached to the Notice of Allowance mailed June 23, 2011, for the above-referenced patent application. It is respectfully requested that Applicants be granted a minimum patent term adjustment of 1471 days.

2. Applicants submit herewith a “Statement Under 37 CFR § 1.702(b).”

3. In accordance with 37 C.F.R. § 1.705(b)(1), Applicants submit payment by Credit Card in the amount of \$200.00 covering the fee set forth in 37 CFR § 1.18(e). The U.S. Patent and Trademark Office is authorized to charge any additional fees that may be required in conjunction

with this submission to Deposit Account Number 50-2228, from which the undersigned is authorized to draw, under Order No. 026038.0265PTUS.

Dated: August 30, 2011

Respectfully submitted,

By /Therese M. Finan/
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STATEMENT UNDER 37 C.F.R. § 1.702(b)

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration Under 37 C.F.R. § 1.705(b)” for the above-referenced patent application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of **1471 days**.
2. The patent term adjustment indicated on the “Determination of Patent Term Adjustment Under 35 U.S.C. 154(b)”, which was attached to the Notice of Allowance mailed June 23, 2011, is 712 days (a copy of which is attached as Exhibit A). This determination of 712 days is in error because, pursuant to 35 U.S.C. §154(b), the Office failed to properly account for the days lost to Patent Office delays under 37 C.F.R. § 1.702(a)(1) and § 1.703(a)(1), in conjunction with the Patent Office’s delays in issuing a patent within three years of filing the above-referenced

application under 37 C.F.R. § 1.702(b) and § 1.703(b), as provided in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010).

3. Pursuant to 37 C.F.R. § 1.702, the correct patent term adjustment should be **at least 1471 days**. The correct patent term adjustment of 1471 days accounts for the delay times for:

- a. failure of the Patent Office to issue a patent within three years of the 35 U.S.C. § 371 National Stage Commencement date (filing date) of August 31, 2006, which totals a delay of 855 days based on a projected January 3, 2012 issuance date, 35 U.S.C. § 154(b)(1)(B), 37 C.F.R. §§ 1.702(b), 1.703(b);
- b. failure of the Patent Office to provide a first action within 14 months of the 35 U.S.C. § 371 completion date of September 2, 2004, wherein the first action was not mailed until October 15, 2006, which totals a delay of 713 days, 35 U.S.C. § 154(b)(1)(A)(i), 37 C.F.R. §§ 1.702(a)(1), 1.703(a)(1); and
- c. failure of the Patent Office to respond within four months to Applicant's Amendment in Response to Non-Final Office Action, dated January 1, 2011, wherein the Patent Office's response, the Notice of Allowance, was not mailed until June 23, 2011, which totals a delay of 51 days, 35 U.S.C. § 154(b)(1)(A)(ii), 37 C.F.R. § 1.702(a)(2), § 1.703(a)(2), (a)(3).

The correct patent term adjustment of 1471 days accounts for 52 days of Applicant delays under 37 C.F.R. § 1.704(b), wherein Applicants were debited:

- a. 34 days for failing to respond to the Non-Final Office Action mailed August 31, 2010 until January 3, 2011 (34 day delay), 35 U.S.C. § 154(b)(2)(C)(ii), 37 C.F.R. § 1.704(b); and

- b. 18 days for submitting a Supplemental Information Disclosure Statement on January 21, 2011, after the January 3, 2011 filing of a response to the Non-Final Office Action mailed August 31, 2010 (18 day delay), 37 C.F.R. § 1.704(c)(8).

The correct patent term adjustment accounts for any overlap regarding the differences between patent term extension periods under 37 C.F.R. § 1.702(b) and § 1.703(b) and all other sections of Code regarding Patent Office Delays, which is set forth under 37 C.F.R. § 1.703(f) regarding calculation of correct patent term adjustments.

4. The above-referenced application is not subject to any terminal disclaimer.
5. There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704 beyond the above-discussed 52 days of Applicants' delay.
6. As set forth in 37 C.F.R. §1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay and examination delay overlap days. Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is **at least 1471 days**, which is the difference between the total period of examination delay (1619 days) and the period of Applicant Delay (52 days) and the period of examination delay overlap days (96 days). **As such, the correct patent term adjustment upon issuance of a patent is expected to be at least the sum of 1471 days (as calculated herein).**
7. Applicants further submit that the patent issuing from the above-referenced application may be entitled to additional patent term adjustment if the patent fails to issue within four

months of payment of the issue fee. 35 U.S.C. § 154(b)(1)(A)(iv), 37 C.F.R. §§ 1.702(a)(5), 1.703(a)(6).

8. In accordance with 37 C.F.R. § 1.705(b)(2)(iii), Applicants submit that the patent issuing from this application will not be subject to a terminal disclaimer.

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of 1471 days. To the extent this petition is dismissed as being premature, Applicants expressly preserve the right to file a petition for patent term adjustment within the specified period after issuance of the patent.

Dated: August 30, 2011

Respectfully submitted,

By /Therese M. Finan/
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Attorney for Applicants

ATTACHMENT:

- (a) Determination of Patent Term Adjustment under 35 U.S.C. §154(b)



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,479	08/31/2006	Lee Terry Bachelor	026038.0265PTUS	5991

93358 7590 06/23/2011
Patton Boggs LLP/ Johnson & Johnson
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McLean, VA 22102

EXAMINER

LIN, JERRY

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/23/2011

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 712 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 712 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.